

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the box label of the article and in the leaflet enclosed in each box were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for irritations of the vaginal tract, vaginal discharge, burning, chafing, and pruritis, and that it would restore normal physiological function of the vagina and re-establish the normal acidity of the vaginal tract. The article was not an adequate and effective treatment for such conditions and would not fulfill the promises of benefit stated and implied. Further misbranding, Section 503 (b) (4), the article was a drug to which Section 503 (b) (1) applied, and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription." The article was misbranded in the above respects when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), certain statements in the leaflet entitled "Mona-Serts Vaginal Tablets Antiseptic—Fungicidal" accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for irritations of the vaginal tract, trichomonas vaginalis vaginitis, mycotic (monilia) vaginitis, and mixed infection vaginitis, and that it would restore normal physiological function of the vagina and re-establish the normal acidity of the vaginal tract. The article was not an adequate and effective treatment for such conditions and would not fulfill the promises of benefit stated and implied. The article was misbranded in such respect while held for sale after shipment in interstate commerce.

DISPOSITION: July 9, 1954. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4428. Misbranding of William's Yukol. U. S. v. 22 Bottles, etc. (F. D. C. No. 36517. Sample No. 84852-L.)

LIBEL FILED: April 21, 1954, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about December 15, 1953, and February 3 and March 19, 1954, from New York, N. Y.

PRODUCT: 22 2-ounce bottles, 52 4-ounce bottles, and 57 8-ounce bottles of *William's Yukol* at Philadelphia, Pa.

RESULTS OF INVESTIGATION: The product, after shipment in interstate commerce, was promoted for sale on the premises of a local Philadelphia store through spiels given by Mrs. Mitze Fanelli, who represented the product for various conditions. In addition to the sales talk, there were displayed on the sales counter 3 letters, each mounted separately on a square of cardboard, containing claims and representations for the product.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment of headaches, migraine headaches, coughs, rheumatism, lumbago, neuritis, arthritis, backache, sinus trouble, fibrositis, myositis, and pain in the feet and legs, which were the conditions and purposes for which the article was offered to the public. The article was misbranded while held for sale after shipment in interstate commerce.

*See also Nos. 4423, 4426.

DISPOSITION: July 28, 1954. Default decree of condemnation and destruction.

4429. Misbranding of glandular products. U. S. v. 40 Vials, etc. (F. D. C. No. 36805. Sample Nos. 90071-L to 90077-L, incl., 90079-L.)

LIBEL FILED: On or about June 1, 1954, Western District of Missouri.

ALLEGED SHIPMENT: On or about August 2, 1951, November 28, 1952, November 16, 1953, and March 14 and 23, 1954, from Chicago, Ill.

PRODUCT: 40 vials of *pituitary anterior aqueous extract*, 60 vials of *ovarian aqueous extract*, 56 vials of *pituitary anterior and ovarian solution*, 20 vials of *orchic tissue aqueous extract*, 45 vials of *pituitary anterior and orchic solution*, 19 vials of *pituitary whole aqueous extract*, 52 vials of *ovarian residue aqueous extract*, and 74 vials of *Spleenæ solution* at Kansas City, Mo., in possession of Henry C. Haist & Co., Inc. The size of each vial was 30 cc.

RESULTS OF INVESTIGATION: The products were shipped in bulk from Chicago, Ill., and upon receipt by the consignee, were repackaged and relabeled.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 9, 1954. Default decree of condemnation and destruction.

4430. Misbranding of aqueous extract of anterior pituitary. U. S. v. 698 Vials * * *. (F. D. C. No. 37023. Sample Nos. 61672-L to 61674-L, incl.)

LIBEL FILED: On or about August 3, 1954, Western District of Missouri.

ALLEGED SHIPMENT: On or about February 17 and March 17, 1953, from Chicago, Ill.

PRODUCT: 698 vials of *aqueous extract of anterior pituitary* at Kansas City, Mo., in possession of Ashe Lockhart, Inc. Some of the vials were labeled and some were unlabeled.

RESULTS OF INVESTIGATION: The article had been shipped in bulk from Chicago, Ill., and after its receipt by the consignee, was repackaged into vials.

LABEL, IN PART: (Vial) "10 c. c. Aqueous Extract Of Anterior Pituitary Each c. c. contains water soluble extractives from 18½ grains fresh tissue. Contains .5% Chlorobutanol (Chloroform Derivative). * * * Distributed by Ashe Lockhart, Inc. Kansas City, Mo."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, and it was not entitled to any exemption from such requirement. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 8, 1954. Default decree of destruction.

4431. Misbranding of orchic substance. U. S. v. 1 Canister, etc. (F. D. C. No. 36818. Sample No. 84853-L.)

LIBEL FILED: June 7, 1954, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about September 23, 1953, and March 1, 1954, from Chicago, Ill.

PRODUCT: 1 5-pound canister of *orchic substance in powder form* and 3 bottles containing *orchic substance in capsules* at Philadelphia, Pa., in possession of Fred F. Wanner & Sons.

RESULTS OF INVESTIGATION: The product, when shipped from Chicago, Ill., was in powder form and packaged in canisters. After receipt of the product by